APPENDIX A

Nos. 06-2286, 06-2301

IN THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

WASHINGTON UNIVERSITY, PLAINTIFF-APPELLEE,

v.

WILLIAM J. CATALONA, DEFENDANT-APPELLANT,

AND

RICHARD WARD, ET AL., DEFENDANTS-APPELLANTS.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, NO. 4:03-CV-1065 THE HON. STEPHEN N. LIMBAUGH, SENIOR DISTRICT JUDGE

OPENING BRIEF FOR DEFENDANT-APPELLANT, WILLIAM J. CATALONA, M.D.

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Lastly, the district court erred in concluding that the patients could not have expected to retain rights in their tissues because two forms expressly waived any claim to the excised tissues. Add. 22. This was misguided for at least three reasons.

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Third, the district court's interpretation of the "waive any claim" language would render the provision void as against public policy. In Missouri, "[a] contract is most often found to be against public policy when its enforcement would defeat or impede statutory regulation of a particular subject matter." 35 MO. PRAC., CONT., EQ. & STAT. ACT. HAND. § 12:8 (2006 ed.); *Barnes v. Boatmen's Nat'l Bank*, 156 S.W.2d 597, 602 (1941). Yet here the district court's reading of the "waive any claim" language runs headlong into the Common Rule, which binds research institutions—including Washington University—that receive federal funding. The Common Rule declares that "[n]o informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive any of the subject's legal rights, or releases or appears to release the investigation, the sponsor, the institution or its agents from liability for negligence." 45 C.F.R. § 46.116.

The U.S. Department of Health and Human Service ("HHS") is actively enforcing the Common Rule right now. For example, HHS sent a letter on January 25, 2006 to Louisiana State University Health Science Center Shreveport directing it to remove the following exculpatory language from its informed consent agreements: "By your consent to participation in this research study, you give up your property

rights that you may have in your bodily fluids, substances or tissues." HHS determined this language was exculpatory in violation of 45 C.F.R. § 46.116 because it made a subject waive or appear to waive his or her legal rights.[9]

As interpreted by the district court, the "waive any claim" language would likewise defeat the Com-

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[9] Letter from Carol J. Weil, Compl. Oversight Coord., Div. of Human Subject Protections, Office of Human Research Protections, to John C. McDonald, Chancellor/Dean, Louisiana State University Health Science Center Shreveport (Jan. 25, 2006) (on file with PHS FOIA Office) *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR06/jan06a.pdf. *See also* Letter from Patrick J. McNeilly, Compl. Oversight Coord., Div. of Compliance Oversight, Office of Human Research Protections, to Fawwaz T. Ulaby, V.P. for Rsch., U. of Mich. (June 29, 2004) (on file with PHS FOIA Office) *avail. at* http://www.hhs.gov/ohrp/detrm_letrs/YR04/jun04c.pdf.

mon Rule's prohibition on research subjects' waivers of their legal rights. The language thus would be void as against public policy.[10]

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[10] The district court also avoided the force of the regulation by glaringly misreading it. To be sure, the court started out on the right foot: "It is clear," the court began, "that [under this language] the only legal obligation [Washington University] had was not to include exculpatory language in its informed consent forms which waived any legal rights the [patients] may have *or* relieve any party from its liability for negligence." Add. 20 (emphasis added). But then the Court asserted—without basis—that "[h]earing testimony from all experts indicated that the research community consistently understood [this regulation] to bar exculpatory language involving releases from malpractice or other negligence." And, without explanation, the district court adopted this reading. Add. 20-21.

This reading, however, cannot be squared with the regulation's plain language. The regulation forbids exculpatory clauses that waive patient rights "or" relieve a party for its negligence. In this Circuit, the disjunctive matters. *See, e.g., Mages v. Johanns*, 431 F.3d 1132, 1140 (8th Cir. 2005) ("The USDA's decision is flawed because it required Mages to show a separate and distinct interest in his land *and* crops, notwithstanding the disjunctive nature of the regulation.") (emphasis in original). Here again, the district court mistakenly relied on expert testimony to interpret a regulation it should have interpreted itself. *See* note 8, *supra*.